



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0972]

Clinical Development Programs for Disease-Modifying Agents for Peripheral Neuropathy;
Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing a scientific public workshop to solicit information on a variety of issues related to the clinical development of disease-modifying agents for the treatment of peripheral neuropathy. Discussion will focus on possible therapeutic targets for these agents, the types of painful peripheral neuropathies amenable to treatment with disease-modifying agents, and clinical trial design. FDA intends to take this information into account in developing FDA guidance on clinical development programs for disease-modifying products for the management of peripheral neuropathy.

Date and Time: The public workshop will be held on February 11, 2013, from 8:30 a.m. to 5 p.m. and February 12, 2013, from 8:30 a.m. to 2 p.m.

Location: The public workshop will be held at FDA White Oak Campus, Building 31, The Great Room (Rm. 1503), White Oak Conference Center, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Entrance for the consultation meeting's participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>

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Registration to Attend the Workshop and Requests to Participate in Open Public Hearing:

As part of the public workshop, an open public hearing will be held between 11 a.m. and 12 p.m. on February 11, 2013. If you wish to attend the public workshop or provide oral comments during the open public hearing, please email your registration to CDER_Neuropathy_Workshop@fda.hhs.gov by February 1, 2013. Those without email access

may register by contacting one of the persons listed in the Contacts section of this document.

Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number.

For those interested in providing oral comments for the open public hearing, please also provide a short abstract of your remarks by February 1, 2013. We will try to accommodate all persons who wish to speak; however, the duration of each speaker's comments during this open public hearing may be limited by time constraints.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at <http://www.fda.gov/Drugs/NewsEvents/ucm310416.htm>.

If you need special accommodations because of a disability, please contact Randi Clark or Allison Meyer (see Contacts) at least 7 days in advance of the public workshop.

Comments: Submit either electronic or written comments by March 11, 2013. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing this public workshop to further the understanding of the development of disease-modifying agents for the treatment of painful peripheral neuropathies. Discussion will focus on possible therapeutic targets for these agents, the types of painful peripheral neuropathies amenable to treatment with disease-modifying agents, and clinical trial design.

FDA will explore the following topics during this public workshop:

1. Pharmacodynamic mechanisms and pharmacogenetic/pharmacogenomic targets of therapeutic agents intended to prevent, slow, modify, arrest, or reverse the course of disease for peripheral neuropathies.

2. Peripheral neuropathy patient populations and study entry criteria for clinical trials designed to evaluate disease-modifying effects of therapeutic agents.

3. Clinically relevant endpoints for trials evaluating therapeutic agents intended to prevent, slow, modify, arrest, or reverse the course of these diseases.

4. Study duration, overall study design, and analysis of clinical trials needed to demonstrate a treatment effect on disease modification for peripheral neuropathy.

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at <http://www.fda.gov/Drugs/NewsEvents/ucm310416.htm>.

II. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division

of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr.,
Element Bldg., Rockville, MD 20857.

Dated: September 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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